

## REMARKS/ARGUMENTS

### *The Invention*

The invention provides an apparatus for jet injection of DNA into cell tissues.

### *The Pending Claims*

Claims 1-6 currently are pending and are directed to an apparatus for jet injection of DNA into cell tissues comprising an injection nozzle, an injection port, a jet propulsion system affixed to a platform wherein injection tubing connects the jet propulsion system to the injection nozzle, and a computer means to position the injection nozzle on the surface of the tissue to be injected.

### *The Office Action*

The Office Action rejects claims 1, 2, 4, 5, and 6 under 35 U.S.C. § 103(a) as allegedly obvious over Dixon (U.S. Patent. No. 4,722,728) in view of Kwoh (U.S. Patent No. 5,078,140). Further, The Office Action rejects claims 1, 3, 4, 5, and 6 under 35 U.S.C. § 103(a) as allegedly obvious over Brown (U.S. Patent. No. 5,167,220) in view of Kwoh (U.S. Patent No. 5,078,140). Finally, the Office Action rejects claims 1-6 under the judicially created doctrine of obviousness-type double patenting as allegedly unpatentable over claims 1-6 of U.S. Patent No. 6,361,991. Reconsideration of these rejections is respectfully requested.

### *Discussion of Rejection Under 35 U.S.C. § 103(a)*

The Office Action rejects claims 1, 2, 4, 5, and 6 under 35 U.S.C. § 103(a) as allegedly obvious and, therefore, unpatentable over Dixon (U.S. Patent. No. 4,722,728) in view of Kwoh (U.S. Patent No. 5,078,140). This rejection is traversed for the reasons set forth below.

The Office Action alleges that Dixon teaches an apparatus for jet injections capable of injecting DNA into cells, comprising an injection nozzle, and injection tubing connecting the nozzle to a jet propulsion system. However, the Office Action acknowledges that Dixon does not disclose attaching the device to a computer-means electrically connected to the platform to position the device at the desired site of injection nor does Dixon disclose an endoscope attached to the device. The Office Action goes on to allege that Kwoh teaches attaching devices to a computer-guided platform to position the device for making injections and attaching an endoscope to the device. The Office Action concludes this rejection by alleging

that a person having ordinary skill in the art would have known to combine the teachings of Kwoh and Dixon to reach the claimed invention. This rejection is respectfully traversed.

Dixon discloses a spring powered, needle-less hypodermic injector for delivering medicine, not an apparatus for jet injections of DNA into cells. In contrast to the teachings of Dixon the instant claims recite an apparatus for the jet injection of DNA into specific tissues. The jet injection apparatus claimed comprises an injection nozzle having at least one injection port, injection tubing connecting the injection nozzle to a jet propulsion system affixed to a platform for positioning the injection nozzle, and a computer means to control the movement of the platform to the desired position of injection. Dixon does not disclose the injection of DNA, let alone the jet injection of DNA. Further, Dixon does not disclose a jet propulsion system nor does Dixon disclose the use of an injection nozzle, which, as is, described in the instant specification, is connected with the jet propulsion system for delivering DNA to the desired location. Finally, Dixon does not disclose injection tubing connecting the injection needle to a jet propulsion system, the addition of an endoscope, affixing an injection device to a platform, or controlling the movement of the platform via computer means.

Kwoh does not cure the many deficiencies of Dixon. Kwoh discloses a computer controlled, robotic arm for use in stereotactic surgery on integral body parts. Kwoh mentions using the robotic arm in conjunction with CT or other imaging devices, but does not disclose nor does Kwoh even suggest the use of a jet propulsion system controlled by a computer for making injections of DNA into desired cells and tissues as recited in the instant claims. Furthermore, there is no motivation in the prior art to combine the computer controlled device of Kwoh with the spring-driven injector of Dixon, or to combine the computer controlled device of Kwoh with a device for the jet injection of DNA.

The Office Action has not pointed to any teaching or suggestion in Dixon or Kwoh that points out that a person having ordinary skill in the art would have been motivated to somehow combine the spring-driven device of Dixon with the computer-driven device of Kwoh. Only with the benefit of hindsight in view of Applicant's disclosure would one skilled in the art selectively choose the limited parts of Dixon and Kwoh to form a jet injection device. Further, even if there were some suggestion or motivation in the art to modify Dixon or Kwoh, there would not have been a reasonable expectation that such a modification would affix to a platform an injection nozzle with a jet propulsion system,

wherein injection tubing connects the nozzle to the propulsion system to deliver DNA to the desired site of administration via computer controlled movement, as claimed. There is simply nothing in the cited art to suggest that a person having ordinary skill in the art would have reasonably expected the needless hypodermic injector of Dixon to successfully be affixed to a platform and controlled via computer means to form an apparatus for the jet injection of DNA to the desired site of administration. Accordingly, the Office Action has not met its burden in establishing a *prima facie* case of obviousness on this basis alone.

Moreover, Dixon and Kwoh, even when viewed in combination, do not teach or suggest all of the elements of rejected claims 1, 2, and 4-6. The pending claims recite the an apparatus for the jet injection of DNA comprising an injection nozzle, injection tubing connecting the nozzle to a jet propulsion system affixed to a platform for position the nozzle, and a computer means to provide movement to the platform. Several elements (e.g. jet injection of DNA, injection tubing, etc...) of the rejected claims are not disclosed in the prior art and would not have been readily apparent to one of ordinary skill in the art.

More specifically, with respect to claim 6, neither Dixon nor Kwoh mention or suggest an apparatus for jet injection of DNA into the human female cervix.

Accordingly, the subject matter of claims 1, 2, 4, 5, and, especially, 6 would not have been obvious in view of the cited art. Applicants, therefore, request withdrawal of the rejection under Section 103(a).

The Office Action rejects claims 1, and 3-6 under 35 U.S.C. § 103(a) as allegedly obvious and, therefore, unpatentable over Brown (U.S. Patent. No. 5,167,220) in view of Kwoh. This rejection is traversed for the reasons set forth below.

The Office Action alleges that Brown discloses a jet injector, nozzle, and a tube connecting the nozzle to the propulsion method, and further comprising an endoscope. The Office Action acknowledges, however, that Brown does not disclose attaching the disclosed device to a computer-means electrically connected to a platform for positioning the device for injecting DNA. Applicants point out that the disclosure of Brown is directed to a nasal sinus endoscope used to force fluid out of the distal end of the tube connected to the endoscope, to keep the lens of the endoscope clean, which is vastly different than the computer-controlled, jet propulsion DNA injector of the instant invention. Brown does not teach a computer controlled fixed platform, and delivery of DNA with the disclosed device. Further,

Applicants point out that Brown does not recite a jet propulsion system as a means for delivering its fluid contents.

Again, Kwoh does not cure the deficiencies of Brown. As discussed above, Kwoh discloses a computer controlled, robotic arm for use in stereotactic surgery on integral body parts. Kwoh mentions using the robotic arm in conjunction with CT or other imaging devices, but does not disclose nor does Kwoh even suggest the use of a jet propulsion system controlled by a computer for making injections of DNA into desired cells and tissues as recited in the instant claims. No motivation to combine the cited references can be found in the prior art and even if the references were combined, every element of the subject claims is not taught or suggested therein. Several elements (e.g. jet injection, the delivery of DNA, etc...) of the rejected claims are not disclosed in the prior art and would not have been readily apparent to one of ordinary skill in the art. Furthermore, the Office Action has not pointed to any teaching or suggestion in Brown or Kwoh that would render obvious the subject matter of claims 1, and 3-5. More specifically, with respect to claim 6, neither Brown nor Kwoh mention or suggest an apparatus for jet injection of DNA into the human female cervix. Likewise, the subject matter of claims 1, 3-5, and especially, 6 cannot properly be considered to have been obvious in view of the cited art. Applicants, therefore, request withdrawal of the rejection under Section 103(a).

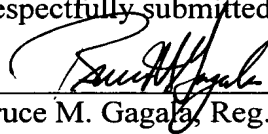
#### *Discussion of Double Patenting Rejection*

The Office Action rejections claims 1-6 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 of U.S. Patent No. 6,361,991. Submitted herewith is a Terminal Disclaimer under 37 C.F.R. § 1.321(b), which is based on U.S. Patent 6,361,991. The enclosed Terminal Disclaimer renders moot this obviousness-type double patenting rejection

#### *Conclusion*

The application is considered in good and proper form for allowance, and the Examiner is respectfully requested to pass this application to issue. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned attorney.

Respectfully submitted,



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